

Regulating the drugs industry transparently

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risk; the preferred remedies are public education about safe drinking, improved policing, better treatment for alcohol problems, and self regulation by the alcohol industry—the policies which evidence suggests are the least likely to reduce problem drinking.⁵⁻⁷

The UK government has foregone the use of the most effective policy to reduce hazardous drinking: using taxation to increase the price of the beverages containing the highest concentrations of alcohol.⁵ It justifies this decision by saying that increased price has not been shown definitely to reduce harm due to alcohol,¹ an assertion at odds with the views of the world's leading researchers on alcohol.⁸⁻¹⁰

The government has also rejected any policies that would reduce the availability of alcohol. Instead, it embraces the paradoxical idea that allowing drinking for up to 24 hours a day for seven days a week will reduce binge drinking and public disorder. It believes that, somehow, longer trading hours will help to create a continental drinking culture in Britain. This proposal has caused understandable consternation among British judges, police, the Royal College of Physicians, medical researchers, and alcohol experts.⁸⁻¹⁰

Experience in Australia suggests that even a government bent on deregulation could do better.⁷ Over the past two decades Australia has expanded alcohol availability, liberalised trading hours, and not increased overall taxation on alcohol. In 1980-2000 in the United Kingdom per capita alcohol consumption increased by 31%, but in Australia it fell by 24%—as did many of the indicators of alcohol related harm that increased so steeply in the United Kingdom.⁷

Australia has imposed lower taxes on low alcohol (less than 3.8%) beer than full strength beer. Also, all states defined drink driving as driving with a blood alcohol concentration over 0.05% (rather than 0.08% as in the United Kingdom). Drink driving laws have also been enforced vigorously by well publicised, large scale random breath testing in the largest states. The immediate and sustained reduction in deaths and serious injuries from road crashes that followed the introduction of random breath testing in the largest

Australian state ensured strong public support for continuing the policy.¹¹ Low alcohol beer now accounts for 40% of all beer consumed in Australia.⁷

The UK government could avoid the worsening epidemic of public drunkenness by not increasing alcohol availability, by lowering taxes on beverages with lower alcohol concentrations, and by reducing the limit for blood alcohol when driving to 0.05%.

If the UK government remains deaf to the arguments of its critics, it should honour its promise to evaluate the effects of its policies. Then it would have the necessary evidence to drop policies that have failed and replace them with policies that have a chance of reducing (rather than merely preventing further rises in) alcohol related harm.

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- 1 Cabinet Office Strategy Unit. *Alcohol harm reduction strategy for England*. London: Strategy Unit, 2004. <http://image.guardian.co.uk/sys-files/Society/documents/2004/03/15/alcoholstrategy.pdf> (accessed 2 Sep 2005).
- 2 Rehm J, Room R, van den Brink W, Jacobi F. Alcohol use disorders in EU countries and Norway: an overview of the epidemiology. *Eur Neuropsychopharmacol* 2005;15:377-88.
- 3 UKATT Research Team. Cost effectiveness of treatment for alcohol problems: findings of the randomised UK alcohol treatment trial (UKATT). *BMJ* 2005;331:544-8.
- 4 UKATT Research Team. Effectiveness of treatment for alcohol problems: findings of the randomised UK alcohol treatment trial (UKATT). *BMJ* 2005;331:541-4.
- 5 Babor T, Caetano R, Casswell S, Edwards G, Geisbrecht N, Graham K, et al. *Alcohol: no ordinary commodity: research and public policy*. Oxford: Oxford University Press, 2003.
- 6 Room R. Disabling the public interest: alcohol strategies and policies for England. *Addiction* 2004;99:1083-9.
- 7 Stockwell T. Australian alcohol policy and the public interest: a brief report card. *Drug Alcohol Rev* 2004;23:377-9.
- 8 Room R. Social policy and psychoactive substances. *Brain science, addiction and drugs research reviews*. London: Foresight Programme, Department of Trade and Industry, 2005.
- 9 Hall C. Doctors say 24-hour opening will worsen drink 'epidemic'. *Daily Telegraph* 2005 Jan 4:1.
- 10 Sengupta S, Hoyle L. Alcohol misuse, public health and public policy. *BMJ* 2005;330:1343-4.
- 11 Henstridge J, Homel R, MacKay P. The long term effects of random breath testing in four Australian states: a time series analysis. Canberra: Federal Office of Road Safety, 1997.

Regulating the drugs industry transparently

The UK government has not gone far enough in responding to a critical inquiry

Over the past 10-15 years, drug regulatory authorities in the United Kingdom and elsewhere have streamlined and accelerated the review of new drugs in response to claims by the pharmaceutical industry that over-regulation was stifling innovation.¹⁻² Despite these policies, the number of new molecular entities—a standard measure of innovation in the industry—submitted to regulatory authorities in the European Union or United States or launched on the world market has fallen overall during the past decade.³⁻⁵

Between 1993 and 2004, almost double the number of drugs were withdrawn from the market in the United Kingdom each year due to lack of safety than in the previous two decades.⁶ The withdrawal of rofecoxib in 2004, affecting millions of patients, remains an enormous public health issue, as do public

concerns about the safety of the widely prescribed selective serotonin reuptake inhibitors.⁷⁻⁸

In this context the House of Commons Health Select Committee began its wide ranging inquiry into the influence of the pharmaceutical industry, publishing its findings on 5 April 2005.⁹ Although the committee acknowledged that the industry makes excellent contributions to medicine and the UK economy, the report also highlighted important concerns about the independence of drug regulation from the interests of the industry; the need to create conditions in which the industry will produce more drugs offering significant therapeutic advance; the industry's over-promotion of its products to doctors; our limited knowledge of drug induced illness; and the cloak of secrecy around UK regulation during the past

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35 years. On 1 September 2005 the government's response to the committee's report showed serious reflection on these issues.¹⁰ The government has accepted many of the committee's recommendations, but too often its response has not gone far enough.

The committee recommended that the Department of Trade and Industry should take responsibility for representing the interests of the pharmaceutical industry, enabling the Department of Health to concentrate solely on the regulation of medicines and the protection and promotion of health. The government rejected this recommendation on the grounds that "the interests of patients and the industry are not exclusive" and that the industry's role in producing innovative medicines beneficial to health should be considered together with its economic investment in the United Kingdom. In this political context there is a considerable risk that public health will not be given sufficient priority whenever the commercial interests of pharmaceutical companies diverge from, or conflict with, health needs.

Since 1996 fewer than half of the drug innovations (new molecular entities) in the United States have offered real therapeutic advances.⁹ Many are "me too" drugs: minor molecular modifications of existing products. They satisfy the technical definition of innovation and seek a slice of a lucrative market, but contribute little or no therapeutic advance for patients. The House of Commons Health Select Committee recommended that the UK Medicines and Healthcare Products Regulatory Agency (MHRA) should be more proactive in stimulating the industry to develop drugs of real therapeutic value and "therapeutic gain." Despite recognising that the existence of a large number of "me too" drugs creates difficulties for prescribers, the government remains unwilling to direct the development of drugs towards more meaningful new treatments.

The committee also felt that the deluge of promotional material doctors receive from pharmaceutical companies is excessive and insufficiently counterbalanced by independent information, especially when the manufacturer seeks to establish a market position for a newly launched drug and patients are most at risk because little is known about the product. The government, on the other hand, believes that the industry's current self regulation of drug promotion is acceptable. Nevertheless, the MHRA may extend its vetting of promotional materials to all new molecular entities and may impose additional restrictions when new drugs are first released on to the market.

The government now seems to embrace the idea of patients reporting their own adverse drug reactions using the Yellow Card scheme that is already used by

prescribers. However, the government ignored the committee's call for the Department of Health and the MHRA to investigate the extent, cost, and implications of drug induced illness in our communities and to pave the way for rational cost-benefit assessment of medicines.

Issues of secrecy, transparency, and public accountability in the drug regulatory system pervaded almost every aspect of the inquiry. The government agrees that the regulatory system should be as transparent as possible. It has promised to provide public access to information on licensing applications for individual drugs, to the data supporting authorisation for marketing, and to assessments of medicines on which regulatory action is taken. This is a considerable and welcome shift in thinking and policy, but these commitments must also be implemented in practice.

The committee recommended that the MHRA should make public the material it receives from drug companies along with its assessments as soon as they are complete. This would enable scientists and doctors to scrutinise and engage with the agency's decision making processes and would ensure that drug regulation was publicly defensible and hence more robust. The government, however, insists on reaching regulatory decisions about applications for new drug licences before allowing any public access to such information. At least, though, the government has agreed that the MHRA should be independently reviewed every four or five years.

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- 1 Abraham J, Lewis G. *Regulating medicines in Europe: competition, expertise and public health*. London: Routledge, 2000.
- 2 Hilts PJ. *Protecting America's health: the FDA, business and one hundred years of regulation*. New York: Knopf, 2003.
- 3 Charles River Associates. Innovation in the pharmaceutical sector: a study undertaken for the European Commission. 2004. http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2004/nov/EU%20Pharma%20Innovation_25-11-04.pdf (accessed 4 Sep 2005).
- 4 Woodcock J. FDA's critical path initiative. 2 Jun 2004. www.fda.gov/oc/initiatives/criticalpath/woodcock0602/woodcock0602.html (accessed 5 Sep 2005).
- 5 CMR International. Latest news: innovation on the wane? 2005. www.cmr.org (accessed 5 Sep 2005).
- 6 Abraham J, Davis C. A comparative analysis of drug safety withdrawals in the UK and the US (1971-1992): implications for current regulatory thinking and policy. *Soc Sci Med* 2005;61:881-92.
- 7 Topol EJ. Failing the public health – rofecoxib, Merck and the FDA. *New Engl J Med* 2004;351:1707-9.
- 8 Department of Health. Press release 2003/0214, 23 May 2003.
- 9 House of Commons Health Committee. *The influence of the pharmaceutical industry*. 22 Mar 2005. www.parliament.the-stationery-office.co.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf (accessed 5 Sep 2005).
- 10 Government response to the Health Committee's report on the influence of the pharmaceutical industry, 1 September 2005. (Cm 6655.) www.dh.gov.uk/assetRoot/04/11/86/08/04118608.pdf (accessed 5 Sep 2005).

SSRIs and gastrointestinal bleeding

Gastroprotection may be justified in some patients

There are theoretical reasons for believing that selective serotonin reuptake inhibitors (SSRIs), widely used to treat depression, might increase the risk of gastrointestinal bleeding. Gastroprotective drugs are advocated for high risk patients taking non-steroidal anti-inflammatory drugs, another class of

drug that causes gastrointestinal bleeding. What is the evidence that this advice should be extended to patients receiving SSRIs?

Serotonin is released from platelets in response to vascular injury and promotes vasoconstriction and a change in the shape of the platelets that leads to